VERSION WITH MARKINGS SHOWING CHANGES MADE TO CLAIMS

- 1. (Amended) [An apparatus] A drug product comprising:
- a drug formulation comprising a mixture of at least a drug and an HFA propellant;
 - a pressurized container filled with said drug formulation; and,
 - a moisture absorbing material located within the pressurized container.
- 2. (Amended) The [apparatus] <u>drug product</u> of claim 1 wherein the pressurized container is a component of a metered dose inhaler.
- 3. (Amended) The [apparatus] <u>drug product</u> of claim 1 wherein the drug is albuterol sulfate.
- 4. (Amended) The [apparatus] <u>drug product</u> of claim 3 wherein the HFA propellant is 134a.
- 5. (Amended) The [apparatus] <u>drug product</u> of claim 2 wherein the moisture absorbing material is a desiccant.
- 6. (Amended) The [apparatus] <u>drug product</u> of claim 5 wherein the desiccant is a material selected from the group consisting of nylon, silica gel, zeolite, alumina, bauxite, anhydrous calcium sulphate, activated bentonite clay, water absorbing clay, molecular sieve and combinations thereof.
- 7. (Amended) The [apparatus] <u>drug product</u> of claim 6 wherein the desiccant is contained within a sachet constructed from a nylon mesh.
- 8. (Amended) The [apparatus] <u>drug product</u> of claim 7 wherein the sachet is loose within the pressurized container.



- 9. (Amended) The [apparatus] <u>drug product</u> of claim 7 wherein the sachet is fixedly attached to the pressurized container.
- 10. (Amended) The [apparatus] <u>drug product</u> of claim 6 wherein the desiccant is in the form of granules or beads suitably large in size to avoid clogging a valve in the metered dose inhaler.
 - 11. (Amended) [An apparatus] A drug product comprising:
- a drug formulation comprising a mixture of at least a drug and an HFA propellant;
 - a pressurized container filled with said drug formulation; and,
 - a moisture absorbing means located within the pressurized container.
- 12. (New) The drug product of claim 1 wherein the drug is fluticasone propionate or a solvate thereof.
- 13. (New) The drug product of claim 1 wherein the drug is beclomethasone dipropionate or a solvate thereof.
- 14. (New) The drug product of claim 1 wherein the drug is a salt, ester or solvate of salmeterol.
- 15. (New) The drug product of claim 1 wherein the drug is a combination of a salt, ester or solvate of salmeterol and a salt, ester or solvate of ipratropium.
- 16. (New) The drug product of claim 1 wherein the drug is a combination of fluticasone propionate or a solvate thereof and a salt, ester or solvate of salmeterol.



REMARKS

Applicants thank the Examiner for the courtesies extended during the in-person interview conducted on July 26, 2001. Applicants acknowledge the Examiner Interview Summary Record.

Claims 1-16 are pending. The claims have been amended to more particularly point out and distinctly claim the subject matter Applicants regard as the invention. New claims 12-16 have been added to more comprehensively, particularly point out and distinctly claim the subject matter Applicants regard as the invention. Support for the claimed invention is found in the application as originally filed. No new matter has been added.

As set forth in the Office Action Summary dated July 3, 2001, claims 1-1 stand rejected. During the interview it was agreed that the filing of a proper Terminal Disclaimer would overcome the obviousness-type double patenting rejections of record. It was further agreed that the claims could be amended to recite a "drug product" in the preamble to more clearly claim a dosage form (i.e., an inhalation device) for delivering a drug.

Obviousness-Type Double Patenting Rejections

At ¶'s 2-3 of the Office Action, claims 1-5 and stand rejected under the judicially-created doctrine of double patenting over claims 2-4 and 9-11 of USPN 6,119,853 (the '853 patent. At ¶4 of the Office Action, claims 1-5 and 11 stand rejected under the judicially-created doctrine of double patenting over claims 1-7 of USPN 6,179,118 (the '118 patent). At ¶5 of the Office Action, claims 1-11 stand provisionally rejected under the judicially-created doctrine of double patenting over claims 21-30 of Applicants co-pending patent application Serial No. 09/599,702.

In view of the attached Terminal Disclaimer, Applicants respectfully request reconsideration and withdrawal of the rejections.



For the above reasons, Applicants respectfully traverse the rejections set forth in the outstanding Office Action and request that they be withdrawn. Applicants respectfully contend that the application is in condition for allowance and requests the same. The Examiner is invited to contact the undersigned should there be any questions or concerns.

Respectfully submitted,

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